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### REMARKS

Applicants respectfully request reconsideration of the present application.

# 1. <u>Disposition of the Claims and Specification</u>

Claims 44-51, 54, and 58-61 are pending. Claims 44, 50 and 51 are currently amended. Claims 61 and 62 are newly added. Support for the amendment to claim 44 may be found in the specification at page 16, line 31 – page 17, line 2. Support for the amendment to claim 51 may be found in the specification at page 17, lines 8-15. Support for claims 61 and 62 may be found in the specification at page 27, lines 17-18. Claim 50 was dependent on a cancelled claim, as a result of a typographical error, and is amended to be dependent on a pending claim.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

# 2. <u>Specification/Information Disclosure Statement</u>

The Examiner indicates that the documents supplied on 1/20/2004 were not considered because they did not comply with 37 C.F.R. § 1.98. Applicants resubmit these documents in the attached information disclosure statement in conformance with 37 C.F.R. 1.98.

# 3. Claim Rejections – 35 U.S.C. § 101

Claims 44-51, 54, and 58-59 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The Examiner reasons that "until some actual and specific significance can be attributed to the protein identified in the specification ... the instant invention is incomplete." Office Action at 3. The Examiner admits that Applicants will satisfy the utility requirement of 35 U.S.C. § 101 by identifying one substantial credible utility, such as an "indicator of a diseased state or of the presence of a disorder." Office Action at 6. Applicants respectfully request reconsideration and withdrawal of the rejection.

According to the results of the attached BLAST search, performed with SEQ ID NO: 3 of the instant invention, the protein identified in the specification having an amino acid sequence corresponding to SEQ ID NO: 3 is identical to the proteins named p34SEI1 and TRIP-Br1. See BLAST Search Results (Exhibit 1). Sugimoto *et al.*, GENES & DEVELOPMENT 13:3027-3033 (1999), a post-filing date article regarding the p34SEI1 protein, indicates that the p34SEI1 protein antagonizes the function of p16INK4a, which inhibits the cyclin-dependent kinases CDK4 and CDK6. See Sugimoto *et al.*, GENES & DEVELOPMENT 13:3027-3033 (1999). Sugimoto *et al.*, on pages 3031-32, explains that as a modulator of CDK4 kinase activity, p34SEI1 can "contribute to the deregulated growth of tumor cells." Along these lines, page 27 of the instant specification states that "expression of CECRP is closely associated with cell proliferation."

Hsu, et al., THE EMBO JOURNAL, Vol. 20, No. 9, pp. 2273-2285 (2001), another post-filing date article, reports that TRIP-Br1 is a transcriptional regulator that stimulates E2F-1/DP-1 transcriptional activity. See Hsu, et al., THE EMBO JOURNAL, Vol. 20, No. 9, pp. 2273-2285 (2001). Hsu, et al., on pages 2282-83, explains that TRIP-Br1 is identical to the cyclin-dependent kinase 4 (cdk4) binding protein p34SEI1, and the BLAST results show that TRIP-Br1 and p34SEI1 are identical to the protein of the instant invention represented by SEQ ID NO: 3.

Accordingly, the claimed proteins and nucleotides of the instant invention do have a determined function with biological significance. Specifically, the claimed protein is related to cell proliferation and CDK4 kinase modulation, as well as transcriptional regulation. Additionally, the claimed protein and nucleotides may be used as a reagent for the diagnosis of a disease involving changes in levels of cyclin-dependent kinases CDK4 and CDK6, or to diagnose a disease implicated by changes in E2F transcriptional activity. Such diseases are disclosed in the specification at page 40. Because the claimed invention has at least one substantial and credible utility, the § 101 rejection is improper and should be withdrawn.

# 4. Claim Rejections – 35 U.S.C. § 112, First Paragraph

Claims 44-51, 54, and 58-59 are rejected under 35 U.S.C. § 112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner reasons that because the claimed invention is not supported by either a substantially asserted utility or a well established utility, one skilled in the art clearly would not know how to use the claimed invention. Applicants have established a substantial and well-established utility as described above. The § 112, first paragraph, rejection is improper and should be withdrawn.

Further, the Examiner has rejected claims 44-51, 54, and 58-59 because the instant specification fails to adequately describe and enable proteins that are at least 90% identical to the polypeptide of SEQ ID NO: 3. Applicants do not agree with the Examiner. However, to expedite prosecution, Applicants have amended claims 44 and 51 to avoid this issue. Support for the amendment to claim 44 may be found in the specification at page 16, line 31 – page 17, line 2. Support for the amendment to claim 51 may be found in the specification at page 17, lines 8-15. The present version of the claims avoids this issue. The rejection should be withdrawn.

### 5. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 44-51, 54, and 58-59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner states that it is unclear what cell cycle regulating activity the claimed protein has. As described above, Applicants have established an actual effect that the claimed protein has on the cell cycle from which one can determine the "metes and bounds of the term 'cell cycle regulating activity.'" See Office Action at 8. Specifically, Applicants have demonstrated that the claimed protein is associated with unregulated growth of tumor cells, i.e., unregulated cellular proliferation. See Specification page 27, lines 17-18 and Sugimoto

et al., pages 3031-32. Therefore, the § 112, second paragraph, rejection is improper and should be withdrawn.

# 6. New Claims

Applicants have added new independent claims 61 and 62 to more particularly point out the invention and distinctly claim the subject matter which applicant regards as the invention. New claims 61 and 62 recite a new limitation that the claimed proteins regulate cell proliferation. Support for new claims 61 and 62 may be found at page 27, lines 17-18 of the specification.

# Conclusion

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or

even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Eve L. Frank

Attorney for Applicant

Registration No. 46,785

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone:

(202) 945-6142

Facsimile:

(202) 672-5399

Enclosure:

Results of BLAST Search

USSN: 09/701,675



# **BLAST2 Search Results**

Sequences	Hel p					4.0
Retrieval	BLAST2	FASTA	ClustalW	GCG Assembly	Phrap	Translation
BLAST 2 Manual						

Confidential -- Property of Incyte Corporation SeqServer Version 4.6 Jan 2002

Program: blastp Sequence ID(s):

236062CD1 vs. genpept137

NCBI-BLASTP 2.0.10 [Aug-26-1999]

1

Reference: Altschul, Stephen F., Thomas L. Madden, Alejandro A. Schaffer, Jinghui Zhang, Zheng Zhang, Webb Miller, and David J. Lipman (1997), "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs", Nucleic Acids Res. 25:3389-3402.

Query= 236062CD1 (236 letters)

Database: genpept137

1,534,369 sequences; 474,463,515 total letters

Searching.........done

Sequences producing significant alignments:	(bits)	E Value
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g21914610 SCDK4-binding protein p34SEI1 [Homo sapiens]	475	e-133
g14029834 TRIP-Br1 [Homo sapiens]	. 475	e-133
g12803669 CDK4-binding protein p34SEI1 [Homo sapiens]	474	e-132
<b>☑</b> g6746617 p34SEI-1 [Mus musculus]	411	e-113
	411	e-113
g14029832 TRIP-Br1 [Mus musculus]	411	e-113
g12835034 unnamed protein product [Mus musculus]	411	e-113
g12842405 unnamed protein product [Mus musculus]	406	e-112
g14029830 TRIP-Br1 [Mus musculus]	381	e-104

>  $\frac{6434876}{2}$  CDK4-binding protein p34SEI1 [Homo sapiens] Length = 236

Score = 475 bits (1210), Expect = e-133 Identities = 236/236 (100%), Positives = 236/236 (100%)

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           MYDNELWAPASEGLKPGPEDGPGKEEAPELDEAELDYLMDVLVGTQALERPPGPGR
Sbjct: 181 MYDNELWAPASEGLKPGPEDGPGKEEAPELDEAELDYLMDVLVGTQALERPPGPGR 236
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Sbjct: 121 DLSHIEGLSQAPQPLADEGPPGRSIGGAAPSLGALDLLGPATGCLLDDGLEGLFEDIDTS 180
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Sbjct: 181 MYDNELWAPASEGLKPGPEDGPGKEEAPELDEAELDYLMDVLVGTQALERPPGPGR 236
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 >g12803669 CDK4-binding protein p34SEI1 [Homo sapiens]
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           EPDLRHLVLVVNTLRRIQASMAPAAALPPVPSPPAAPSVADNLLASSDAALSASMASLLE 120
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Sbjct: 61
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Query: 181 MYDNELWAPASEGLKPGPEDGPGKEEAPELDEAELDYLMDVLVGTQALERPPGPGR 236
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>g6746617 p34SEI-1 [Mus musculus]
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Query: 1
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Sbjct: 1
           EPDLRHLVLVVNTLRRIQASMAPAAALPPVPSPPAAPSVADNLLASSDAALSASMASLLE 120
Query: 61
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Sbjct: 61
Query: 121 DLSHIEGLSQAPQPLADEGPPGRSIGGAAPSLGALDLLGPATGCLLDDGLEGLFEDIDTS 180
           DL+HIE L+QAPQP ADEGPPGRSIGG +P+LGALDLLGPATGCLLDDGLEGLFEDIDTS
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Query: 181 MYDNELWAPASEGLKPGPEDGPGKEEAPELDEAELDYLMDVLVGTQALERPPGPGR 236
           MYD+ELW PASEGLKPGPE+GP KEE PELDEAELDYLMDVLVGTQALERPPGPGR
Sbjct: 181 MYDSELWLPASEGLKPGPENGPAKEEPPELDEAELDYLMDVLVGTQALERPPGPGR 236
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Query: 181 MYDNELWAPASEGLKPGPEDGPGKEEAPELDEAELDYLMDVLVGTQALERPPGPGR 236
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MYD+ELW PASEGLKPGPE+GP KEE PELDEAELDYLMDVLVGTOALERPPGPGR

Sbjct: 181 MYDSELWLPASEGLKPGPENGPAKEEPPELDEAELDYLMDVLVGTQALERPPGPGR 236

```
>g14029832 TRIP-Br1 [Mus musculus]
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Score = 411 bits (1044), Expect = e-113
Identities = 204/236 (86%), Positives = 214/236 (90%)
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- Sbict: 1 MLSKGLKRKREEEETMEALSVDSCWLDPSHPAVAQTPPTVASSSLFDLSVVKLHHSLRQS 60
- Suject. 1 implication of the superior of the s
- Query: 61 EPDLRHLVLVVNTLRRIQASMAPAAALPPVPSPPAAPSVADNLLASSDAALSASMASLLE 120 EPDLRHLVLVVNTLRRIQASM PA LPP P P APSVAD+LLASSDA LSASMASLLE
- Sbjct: 61 EPDLRHLVLVVNTLRRIQASMEPAPVLPPEPIQPPAPSVADSLLASSDAGLSASMASLLE 120
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- Query: 181 MYDNELWAPASEGLKPGPEDGPGKEEAPELDEAELDYLMDVLVGTQALERPPGPGR 236
  - MYD+ELW PASEGLKPGPE+GP KEE PELDEAELDYLMDVLVGTQALERPPGPGR
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- Sbjct: 61 EPDLRHLVLVVNTLRRIQASMEPAPVLPPEPIQPPAPSVADSLLASSDAGLSASMASLLE 120
- Query: 121 DLSHIEGLSQAPQPLADEGPPGRSIGGAAPSLGALDLLGPATGCLLDDGLEGLFEDIDTS 180 DL+HIE L+QAPQP ADEGPPGRSIGG +P+LGALDLLGPATGCLLDDGLEGLFEDIDTS
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- Sbjct: 181 MYDSELWLPASEGLKPGPENGPAKEEPPELDEAELDYLMDVLVGTQALERPPGPGR 236

#### >g12842405 unnamed protein product [Mus musculus] Length = 236

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- Sbict: 61 EPDLRHLVLVVNTLRRIQASMEPAPVLPPEPIQPPAPSVADSLLASSDAGLSASMASLLE 120
- Query: 121 DLSHIEGLSQAPQPLADEGPPGRSIGGAAPSLGALDLLGPATGCLLDDGLEGLFEDIDTS 180 DL+HIE L+QAPQP ADEGPPGRSIGG +P+LGALDLLGPATGCLLDDGLEGLFEDIDTS
- Sbjct: 121 DLNHIEDLNQAPQPQADEGPPGRSIGGISPNLGALDLLGPATGCLLDDGLEGLFEDIDTS 180

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Query: 61
Sbjct: 61 EPDLRHLVLVVNTLRRIQASMEPAPVLPPEPIQPPAPSVADSLLASSDAGLSASMASLLE 120
Ouery: 121 DLSHIEGLSQAPQPLADEGPPGRSIGGAAPSLGALDLLGPATGCLLDDGLEGLFEDIDTS 180
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Lambda
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Gapped
Lambda
           K
           0.0470
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                      0.230
Matrix: BLOSUM62
Gap Penalties: Existence: 11, Extension: 1
Number of Hits to DB: 250279773
Number of Sequences: 1534369
Number of extensions: 11255951
Number of successful extensions: 47209
Number of sequences better than 10.0: 220
Number of HSP's better than 10.0 without gapping: 34
Number of HSP's successfully gapped in prelim test: 192
Number of HSP's that attempted gapping in prelim test: 46850
Number of HSP's gapped (non-prelim): 418
length of query: 236 length of database: 474,463,515
effective HSP length: 59
effective length of query: 177
effective length of database: 383,935,744
effective search space: 67956626688
effective search space used: 67956626688
T: 11
A: 40
X1: 16 ( 7.2 bits)
X2: 38 (14.8 bits)
```

X3: 64 (24.9 bits) S1: 42 (21.7 bits)



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